

- Claims 1-3, 11-12, 17, and 18 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,994,066 to Voss (“Voss”);
- Claims 4-5 and 7-9 under 35 U.S.C. §103(a) as being unpatentable over Voss in view of U.S. Patent No. 4,955,859 to Zilber (“Zilber”);
- Claims 6 under 35 U.S.C. §103(a) as being unpatentable over Voss in view Zilber further in view of U.S. Patent No. 5,246,445 to Yachia *et al.* (“Yachia.”);
- Claim 10 under 35 U.S.C. §103(a) as being unpatentable over Voss in view of U.S. Patent No. 5,269,802 to Garber (“Garber”).

In light of the remarks presented herein, Applicants respectfully traverse the outstanding rejections and respectfully request reconsideration and withdrawal of all grounds of rejection of pending claims. Applicants further submit that newly added claims are patentable over the references of record.

Amendments to the Claims

Applicants amend claims 1, 4, and 9, and add new claims 38-51 to more particularly point out and distinctly claim the subject matter Applicants regard as their invention, as well as to correct typographical errors in the claims. No new matter has been introduced by these amendments. Specifically, support for amendments to claims 1, 4, and 9 can be found in these claims as originally filed.

Also, new independent claim 38 includes most of the limitations of the original claim 4, rewritten in independent form including all limitations of the base claim 1. Further, new independent claim 51 is identical in scope to the original claim 9, rewritten in independent form including all limitations of the base claim 1. Finally, support for new dependent claims 39-50 recite can be found in claims 2-12 and 17-18 as originally filed.

Further, the USPTO previously required Applicants to elect one of four perceived inventive concepts to which the claims had to be restricted. In response, Applicants elected, with traverse, claims 1-18 generally drawn to stents, and hereby cancel the rest of the original claims without prejudice and without any intention of abandoning the subject matter thereof

Finally, claims 13-16 have been withdrawn from consideration as being drawn to unelected species. It is understood that these non-elected claims depending from otherwise allowable base claims, while withdrawn from consideration, remain pending and will be allowable upon allowance of the base claims.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 1 and all claims dependent therefrom stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite because, as pointed out by the Examiner, it was not clear whether the “first and second ends” recited therein refer to previously recited “first and second terminal ends.” Applicants hereby amend claim 1 and submit that, as amended, claim 1 duly complies with the requirements of 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. §102(b)

Claims 1-3, 11-12, 17, and 18 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Voss. Applicants respectfully traverse this rejection, and submit that Voss fails to teach every limitation of independent claims 1, as amended, or claims dependent either directly or indirectly therefrom.

In order for a claim to be anticipated under 35 U.S.C. §102(b), each and every limitation thereof must be found in a single reference. Applicants respectfully submit that Voss fails to meet this exacting standard as applied to Applicants’ claims, as explained in detail below.

Specifically, independent claim 1 recites, in relevant part, “the wall, having a first outside cross-sectional diameter at the first terminal end, a second outside cross-sectional diameter at the second terminal end, and at least one intermediate outside cross-sectional diameter at an intermediate location between the first and second terminal ends, each of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter” (emphasis added).

Voss fails to teach the configuration of the cross-sectional diameters of the wall of the prostatic stent recited in claim 1. Instead, Voss discloses a stent having a cylindrical conduit 12 having a conically shaped flange 14 at one end and an annularly shaped flange 16 at the other

end. See Voss, col. 3, lines 59-63 and Figure 1. Thus, Voss discloses a stent having a conical portion and a conduit of constant outer diameter extending between the conical portion and the annular flange. Moreover, Voss explains that the annular flange 16 (as opposed to conical flange) is the most appropriate at the second end of the stent, in part, because, in part, "the structure of the membranous portion of the urethra is not such to accommodate a conical flange." Voss, col. 4, lines 22-29. In contrast, the wall of the Applicants' stent recited in claim 1 has three distinct portions, where each of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter.

see fig 5
• Wall is outer surface
• terminal ends are at ends of the flange

Thus, since Voss does not, expressly or inherently, teach or suggest the wall, having a first outside cross-sectional diameter at the first terminal end, a second outside cross-sectional diameter at the second terminal end, and at least one intermediate outside cross-sectional diameter at an intermediate location between the first and second terminal ends, each of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter," recited in the amended claim 1, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 1 based on that reference. Because claims 2-18 directly or indirectly depend from independent claim 1 and recite further limitations thereon, Applicants also request that the Examiner reconsider and withdraw any rejection of these claims based on Voss.

Rejection Under 35 U.S.C §103(a)

Dependent claims 4-5 and 7-9 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Voss in view of Zilber. Also, dependent claim 6 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Voss and Zilber, further in view of Yachia. Finally, dependent claim 10 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Voss in view Garber.

Applicants respectfully request reconsideration and withdrawal of these rejections because Voss, Zilber, Yachia, and/or Garber, or any other reference of record, either alone or in proper combination, fail to teach or suggest every element recited in claims 4-10, dependent from claim 1, as amended.

Furthermore, Applicant respectfully submit that Voss, Zilber, Yachia, and/or Garber, or any other reference of record, either alone or in proper combination, do not teach or suggest every element recited in new independent claim 38 (substantially identical in scope to claim 4, as filed) and all claim dependent therefrom or in new independent claim 51.

Claims 4-10

Claims 4-10, which depend either directly or indirectly from the independent claim 1, and include further limitations thereon, stand rejected under 35 U.S.C. § 103(a) as unpatentable over Voss in combination with Zilber, Yachia, and/or Garber. Applicants hereby amended claim 1, however, and, as explained above, Voss does not, expressly or inherently, teach the wall, having a first outside cross-sectional diameter at the first terminal end, a second outside cross-sectional diameter at the second terminal end, and at least one intermediate outside cross-sectional diameter at an intermediate location between the first and second terminal ends, each of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter,” recited in the amended claim 1.

Conversely, Zilber, Yachia, and Garber each fails to remedy the deficiencies of Voss at least because these references also fail to teach or suggest the configuration of the cross-sectional diameters of the wall of the prostatic stent recited in the amended claim 1. Zilber, for example, discloses a stent 10 that includes a generally tubular body 12 having a frustoconically shaped flange 14 at its upper end 16. See Zilber, col. 3, line 68 to col. 4, line 2 and Figures 1,2. Also, Yachia merely describes a spatial spiral of elongate axial extension wound of thin wire having attachment means at each end. See Yachia, col. 4, lines 12-15. Finally, Garber discloses a stent 10 that includes a first ring 10 coupled to a second ring 14 of a smaller diameter, where the first ring 10 and the second ring 14 are joined together by a plurality of connecting arms 16 so that the rings 12,14 are maintained in a co-planar relationship. See Garber, col. 4, lines 44-50 and Figures 1,2. None of these references teaches or suggests “the wall having a first outside cross-sectional diameter at the first terminal end, a second outside cross-sectional diameter at the second terminal end, and at least one intermediate outside cross-sectional diameter at an intermediate location between the first and second terminal ends, each of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter,” recited in the amended claim 1.

Thus, Applicants respectfully submit that claims 4-10 are patentable over Voss in view of Zilber, Yachia, and Garber (as well as over all other references of record), at least because none of these references, alone or in proper combination, teaches or suggests every element of these claims. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 4-10 based on Voss in view of Zilber, Yachia, and/or Garber.

Claims 38-51

As mentioned above, the Office Action rejected dependent claims 4 and 9 under 35 U.S.C. § 103(a) as unpatentable over Voss in view of Zilber. Applicants respectfully submit that new independent claim 38, which is substantially identical in scope to claim 4, as originally filed, and all claims dependent therefrom, as well as new independent claim 51, identical in scope to claim 9, as originally filed, are patentable over Voss in view of Zilber, Yachia, and/or Garber, because these references, either alone or in proper combination, fail to teach or suggest every element recited in these claims.

Specifically, claim 38 recites, in relevant part, “a stent comprising first and second terminal ends spaced apart from each other, at least one of the first and second terminal ends comprising a retention ring having an expanded ring state and a collapsed ring state” (emphasis added).

Also, claim 51 recites, in relevant parts, “a stent comprising a first terminal end including a first retention ring, the first retention ring having a first expanded ring state and a first collapsed ring state” and “a second terminal end spaced apart from the first terminal end and including a second retention ring, the second retention ring having a second expanded second ring state and a second collapsed ring state” (emphasis added).

The Office Action states, on page 4, that Voss discloses a prostatic stent meeting the structural limitations of claims 4-5 and 7-9, but lacks the express disclosure of retention rings having annular elastic cores and expanded and collapsed states. The Office Action goes on to state that Zilber “adds retention rings with annular elastic cores along the length of the stent to provide reinforcement of the stent once implanted.”

Applicants agree with the Examiner that Voss fails to teach or suggest a stent at least one of whose first and second terminal ends includes a retention ring having an expanded ring state

and a collapsed ring state, recited in claims 38 and 51. Contrary to the quoted statement in the Office Action, however, Zilber fails to remedy the deficiencies of Voss at least because Zilber also fails to teach or suggest either “a stent comprising first and second terminal ends spaced apart from each other, at least one of the first and second terminal ends comprising a retention ring having an expanded ring state and a collapsed ring state,” recited in claim 38, or “a stent comprising a first terminal end including a first retention ring, the first retention ring having a first expanded ring state and a first collapsed ring state” and “a second terminal end spaced apart from the first terminal end and including a second retention ring, the second retention ring having a second expanded second ring state and a second collapsed ring state,” recited in claim 51.

Rather, as mentioned above, Zilber discloses a stent 10 that includes a generally tubular body 12 having a frustoconically shaped flange 14 at its upper end 16. See Zilber, col. 3, line 68 to col. 4, line 2 and Figures 1,2. The stent 10 further comprises an axial lumen 26 running longitudinally therethrough. See Zilber, col. 4, lines 17-19 and Figure 2. An internally positioned helical spring 28 surrounds the lumen 26 and extends from the upper end 16 of the stent to approximately one centimeter from the lower end of the stent. See Zilber, col. 4, lines 19-23. Zilber further discloses that the steel spring 28 reinforces the stent and renders it radiographically opaque. See Zilber, col. 4, lines 22-26.

Applicants respectfully submit that none of the ends of the stent disclosed by Zilber includes a retention ring having an expanded ring state and a collapsed ring, because Zilber merely discloses a helical spring that reinforces most of the body of the stent. Zilber’s helical spring, however, does not extend to either the flange 14 or the lower end of the stent.

Applicants respectfully submit that Yachia and Garber both fail to remedy the deficiencies of Voss as well, at least because these references also fail to teach or suggest either “a stent comprising first and second terminal ends spaced apart from each other, at least one of the first and second terminal ends comprising a retention ring having an expanded ring state and a collapsed ring state,” recited in claim 38, or “a stent comprising a first terminal end including a first retention ring, the first retention ring having a first expanded ring state and a first collapsed ring state” and “a second terminal end spaced apart from the first terminal end and including a

second retention ring, the second retention ring having a second expanded second ring state and a second collapsed ring state,” recited in claim 51.

Thus, Applicants respectfully submit that claims 38 and 51 are patentable over Voss in view of Zilber, Yachia, and/or Garber (as well as over all other references of record), at least because none of the references, alone or in proper combination, teaches or suggests every element recited in independent claims 38 and 51. Because claims 39-50 depend from claim 38, and recite further limitations thereon, Applicants respectfully submit that these claims are allowable as well.

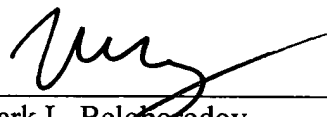
CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration, withdrawal of all grounds of rejection and objection, and allowance of claims 1-12, 17-18, and 36-51 in due course. The Examiner is invited to contact Applicants’ undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

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MARKED-UP VERSION OF THE AMENDED CLAIMS

1. (Amended) A stent comprising,
first and second terminal ends spaced apart from each other, and
a wall, disposed between the first and second terminal ends, and including an
inner surface and an outer surface, the inner surface defining a lumen extending between
the first and second terminal ends, and the outer surface having a substantially smooth
portion, the wall having,
a first outside cross-sectional diameter at the first terminal end, a second
outside cross-sectional diameter at the second terminal end, [and] at least one
intermediate outside cross-sectional diameter at an intermediate location between
the first and second terminal ends, wherein [at least one] each of the first and
second outside cross-sectional diameters is greater than the intermediate outside
cross sectional diameter, and
an expanded state and a collapsed state, the wall being adapted to
spontaneously revert from the collapsed state to the expanded state.
4. (Amended) A stent according to claim 1, wherein at least one of the first and second
terminal ends includes a retention ring[,] having an expanded ring state and a collapsed
ring state, the retention ring [and] being adapted to spontaneously revert from the
collapsed ring state to the expanded ring state, and, in the expanded ring state, the
retention ring extending axially from the wall of the stent.
9. (Amended) A stent according to claim 1 wherein
the first terminal end includes a first retention ring[,] having a first expanded ring state
and a first collapsed ring state[, in the first expanded ring state, the first retention ring extending
axially from the wall of the stent,] and being adapted to spontaneously revert from the first
collapsed ring state to the first expanded ring state to facilitate retention of the first retention ring
within the bladder of the patient, the first retention ring extending axially from the wall of the
stent in the first expanded ring state, and wherein
the second terminal end includes a second retention ring[,] having a second expanded
second ring state and a second collapsed ring state[, in the second expanded ring state, the second

retention ring extending axially from the wall of the stent,] and being adapted to spontaneously revert from the second collapsed ring state to the second expanded ring state to inhibit the second retention ring from passing through the external sphincter of the prostatic urethra of the patient, the second retention ring extending axially from the wall of the stent in the second expanded ring state.